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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,925

03/11/2004

Glenn Kawasaki

NATH-003

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24353

7590

05/01/2006

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EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/799,925	Applicant(s) KAWASAKI ET AL.	
	Examiner Dana Shin	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Applicant's Election

Applicant's election with traverse of claims 1-23 in the reply filed on March 3, 2006 is acknowledged. The traversal is on the ground(s) that there is no unduly burdensome search on all claims of the instant application. This is not found persuasive because the method of group I and the system/kit of group II would require different key word searches, which would pose a search burden on the examiner. For instance, key words such as siRNA, shRNA, relative quantifying are not necessarily required for prior art searches for group II, and similarly, key words such as detection reagents, PCR reagents, and ligase are not necessarily required for prior art searches for group I. The requirement is still deemed proper and is therefore made FINAL.

Claims 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 3, 2006.

Upon further consideration, the instantly elected claims 1-23 are considered to contain distinct inventions.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 and 7-17, drawn to a method of quantifying the amount of a target nucleic acid, wherein said target nucleic acid is single-stranded nucleic acid that is NOT an siRNA or shRNA molecule, classified in class 435 subclass 4.

If this group is elected, applicants are further required to elect a single type of target nucleic acid from the following group: 1) peptide nucleic acid, 2) locked nucleic

acid, 3) methylated nucleic acid, 4) nucleic acid conjugate, 5) thio-nucleic acid, and 6) morpholino nucleic acid, as recited in claim 17. See below for reasons.

- II. Claims 1, 5-6, and 18-23, drawn to a method of quantifying the amount of a target nucleic acid, wherein said target nucleic acid is an siRNA or shRNA molecule, classified in class 435 subclass 4.

The inventions are distinct, each from the other because:

Inventions I and II are directed to related process. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, both groups I and II are directed to a method of quantifying the amount of a target nucleic acid. However, the methods of groups I and II are distinct because the target nucleic acids of these two groups have a materially different design, and mode of operation. The target nucleic acid of group I is a single-stranded ribonucleic acid, while that of group II is an siRNA or shRNA molecule. An siRNA or shRNA molecule is a duplex RNA molecule that elicits RNAi-mediated gene suppression via RISC formation, which is not a core structural and functional feature of the single-stranded nucleic acid of group I. Therefore, groups I and II do not overlap in scope and are not obvious variants. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner, and restriction for the examination purpose as indicated is proper therefore.

Modified nucleic acids, peptide nucleic acid, locked nucleic acid, methylated nucleic acid, nucleic acid conjugate, thio-nucleic acid, and morpholino nucleic acid as recited above, are directed to nucleic acids. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each type of nucleic acid above has distinct features that are not shared by another. A peptide nucleic acid is a DNA analogue, in which the backbone is a pseudopeptide rather than a sugar; locked nucleic acid is a nucleic acid analogue, in which the ribose ring is locked into a rigid C3'-*endo* (or Northern-type) conformation; methylated nucleic acid is assembled into a chromatin structure that inhibits transcription; nucleic acid conjugate is a product of conjugating small molecules or large biomacromolecules to oligonucleotides; thio nucleic acid is a nucleic acid, in which thionucleotides are incorporated within a RNA (DNA) chain; and morpholino nucleic acid possesses a non-ionic backbone, in which the ribose sugar is replaced by a 6-membered morpholine moiety. Since these nucleic acids have unique chemical, physical and biological properties, they are mutually exclusive, are not obvious variants, and have a materially different design. Because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner, and restriction for the examination purpose as indicated is proper therefore. Note this is not a species election.

Linked Inventions

Claim 1 links methods of inventions I-II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election of Species

Claim 1 is generic to the following disclosed patentably distinct species: PCR, isothermal amplification, rolling circle amplification, and branched DNA, as recited in claim 12. The species are independent or distinct because each method of amplification has unique steps that are not required by another. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana Shin
Examiner
Art Unit 1635

D. Shin

4-28-2006

J. Schultz
JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER